

# Exhibit B

*State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v.  
Abbott Labs, Inc. et al., Civil Action No. 03-11226-PBS*

**Exhibit to the November 25, 2009 Declaration of Christopher C. Palermo  
in Support of Mylan's Motion for Partial Summary Judgment**

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T-087 P 23/85 F-080

UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF THE DISTRICT OF COLUMBIAFEDERAL TRADE COMMISSION  
600 Pennsylvania Avenue, N.W.  
Washington, D.C. 20580

Plaintiff,

MYLAN LABORATORIES, INC.  
130 Seventh Street  
1030 Century Building  
Pittsburgh, Pennsylvania 15222CAMBEX CORPORATION  
One Meadowlands Plaza  
East Rutherford, New Jersey 07073PROFARMACO S.R.L.  
Via Cucchiari 17  
Milano, ItalyGYMA LABORATORIES OF AMERICA, INC.  
135 Catiagua Rock Road  
Westbury, New York 11590

Defendants

CASE NUMBER 1:98CV03114

JUDGE: Thomas P. Hogan

PU DECK TYPE: Antitrust

CI DATE STAMP: 12/22/98

**COMPLAINT FOR INJUNCTIVE AND OTHER EQUITABLE RELIEF**

Plaintiff the Federal Trade Commission (the "Commission") alleges as follows

1. The Commission brings this action under Section 13(b) of the Federal Trade Commission Act (the "FTC Act"), 15 U.S.C. § 53(b), to secure a permanent injunction and other equitable relief against defendants Mylan Laboratories, Inc. ("Mylan"), Cambrex Corporation

Dec-22-98 04:29PM FROM: ROGERS & WELLS SUPPORT SERVICES

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T-087 P 24/88 F-080

1 Camorex, Pharmacia, Sandoz, Protamabo, and Gynta Laboratories of America, Inc.  
2 (Gynta) collectively defendants, for their unfair methods of competition in or affecting  
3 commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

#### JURISDICTION AND VENUE

4 This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C.  
5 §§ 45 (a) and 53(b) and 28 U.S.C. §§ 1331, 1337(a) and 1345.

6 This Court has personal jurisdiction over each of the defendants pursuant to 15  
7 U.S.C. § 53(b), and because each of the defendants has the requisite constitutional contacts with  
8 the United States of America and with the District of Columbia.

9 Venue in this district is proper under 15 U.S.C. § 53(b) and 28 U.S.C. § 1391(c).

10 The defendants' unfair methods of competition alleged herein are "in or affecting  
11 commerce" within the meaning of Section 4 of the FTC Act, 15 U.S.C. § 44.

#### THE PARTIES

12 Plaintiff Commission is an administrative agency of the United States government  
13 established, organized, and existing pursuant to the FTC Act, 15 U.S.C. §§ 41 *et seq.*, with its  
14 principal offices at 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The Commission  
15 is vested with authority and responsibility for enforcing, *inter alia*, Section 5 of the FTC Act, and  
16 is authorized under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to initiate court proceedings  
17 to enjoin violations of the FTC Act.

18 Defendant Mylan is a corporation organized, existing, and doing business under  
19 and by virtue of the laws of Pennsylvania. Mylan's office and principal place of business is  
20 located at 130 Seventh Street, 1030 Century Building, Pittsburgh, Pennsylvania 15222. Mylan is

Dec-22-88 04:30pm From: ROGERS &amp; WELLS SUPPORT SERVICES

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T-087 P 25/85 F-090

engaged in the business of developing, identifying, manufacturing, marketing, and distributing generic and proprietary pharmaceutical and wound care products, including at least 91 generic drugs. In the twelve months ending March 31, 1998, Mylan had revenues of \$555.4 million and net income of \$100.7 million. Mylan Pharmaceuticals, Inc., a wholly owned subsidiary of Mylan Laboratories, is one of the world's largest generic drug companies. Mylan Laboratories has ultimate control over the activities of Mylan Pharmaceuticals.

8 Defendant Cambrex is a corporation organized, existing, and doing business under and by virtue of the laws of Delaware. Cambrex's office and principal place of business is located at One Meadowlands Plaza, East Rutherford, New Jersey 07073. Cambrex is engaged in the business of manufacturing and selling chemicals for pharmaceuticals, cosmetics, agriculture, and other industrial uses. In 1997, Cambrex had revenues of \$380 million and net income of \$17.8 million. Cbm Technologies, Inc. ("Cbm") is a subsidiary of Cambrex located at 1 East 1st Street, Reno, Nevada 89501. Upon information and belief, Cbm was the primary contracting party, on behalf of Cambrex, in the exclusive licensing arrangements with Mylan described below. Cambrex has ultimate control over the activities of Cbm.

9 Defendant Profarmaco S.r.l., a wholly owned subsidiary of Cambrex, is based in Milan, Italy. Profarmaco is engaged in the business of manufacturing chemicals, including active pharmaceutical ingredients ("APIs"), and selling them to drug manufacturers in the United States and elsewhere. The API, which is the chemical that allows the drug to affect the body, is the most essential raw material for a pharmaceutical product. Cambrex has ultimate control over the activities of Profarmaco.

Dec-22-98 04:30pm From:ROGERS &amp; WELLS SUPPORT SERVICES

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T-067 P 26/85 F-080

10 Defendant Gyma is a corporation organized, existing, and doing business under and by virtue of the laws of New York. Gyma's office and principal place of business is located at 133 Cantiague Rock Road, Westbury, New York 11590. Gyma is engaged in the business of selling APIs and other chemicals to the pharmaceutical industry. In 1997, Gyma had sales of approximately \$91 million. Gyma buys APIs from Protarmaco and other firms and resells them to generic drug manufacturers in the United States.

#### TRADE AND COMMERCE

11 Generic drugs, which are chemically identical versions of branded drugs, cannot be marketed until after the patent on the branded drug has expired. Firms that manufacture and market generic drugs often specialize in such drugs, although Mylan manufactures both generic and branded drugs. Generic drugs typically are sold at substantial discounts from the price of branded drugs.

12 Mylan and other generic drug manufacturers require the approval of the United States Food and Drug Administration ("FDA") to market a generic product in the United States. For each generic drug, the manufacturer must file an Abbreviated New Drug Application ("ANDA") with the FDA to establish that its version of the drug is therapeutically equivalent to the innovator drug. FDA approval of an ANDA takes an average of about 18 months, although the approval process can take two years or more.

13 Typically the generic manufacturer purchases the API from a specialty chemical manufacturer ("API supplier"). The generic manufacturer combines the API with inactive fillers, binders, colorings, and other chemicals to produce a finished product.

Dec-22-08 04:30pm From:ROGERS &amp; WELLS SUPPORT SERVICES

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T-067 P 27/85 F-080

14 To sell an API in the United States, the API supplier must file a Drug Master File (DMF) with the FDA. The DMF explains the processes that the API supplier uses to make the API and to test chemical equivalence and bioequivalence to the brand product. To use an API, the generic manufacturer must file an ANDA that refers to the API supplier's DMF filed with the FDA. More than one drug manufacturer can reference the DMF of the same API supplier. A generic manufacturer that wants or needs to change its API supplier must obtain FDA approval of an ANDA supplement, which includes a reference to the new supplier's DMF and test results regarding the generic manufacturer's product using the new API. This process can take as long as three years, with an average of about eighteen months.

15 Lorazepam and clorazepate are two of the approximately 91 generic drugs that Mylan currently manufactures and sells in tablet form. Lorazepam is used to treat anxiety, tension, agitation, and insomnia, and as a preoperative sedative. Doctors issue over 18 million prescriptions a year for lorazepam tablets. Because lorazepam is used to treat chronic conditions and is heavily prescribed for nursing home and hospice patients, lorazepam users tend to stay on the drug for long periods of time. Clorazepate is used to treat anxiety, as well as hypertension, and in adjunct therapy for nicotine and opiate withdrawal. Doctors issue over three million prescriptions a year for clorazepate tablets.

16 Profarmaco, which manufactures APIs in Italy, holds DMFs for lorazepam API and clorazepate API, and has supplied such APIs to drug manufacturers in the United States. Foreign firms, like Profarmaco, that supply APIs to the United States typically have distributors in the United States who purchase APIs and resell them to generic drug manufacturers in the United States. Mylan purchases its lorazepam and clorazepate API from Gyma, Profarmaco's U.S.

Dec-22-98 04:31pm From: ROGERS &amp; WELLS SUPPORT SERVICES

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T-067 P 28/85 F-090

distributor of these products. Several other generic drug manufacturers have purchased lorazepam API from SST Corporation, a U.S. distributor of this product. SST purchases lorazepam API from Fabbrica Italiana Sintetica ("FIS"), an Italian manufacturer. Mylan has never purchased FIS's lorazepam API from SST because FIS is not an approved lorazepam supplier for Mylan. Mylan's ANDA does not reference FIS's DMF.

#### RELEVANT MARKETS

17 There are four relevant markets: (1) the market for generic lorazepam tablets approved for sale in the United States; (2) the market for generic clonazepam tablets approved for sale in the United States; (3) the market for lorazepam API approved for sale in the United States; and (4) the market for clonazepam API approved for sale in the United States.

#### ANTICOMPETITIVE CONDUCT

18 The defendants' conspiracies, other agreements, and other acts and practices, as herein alleged, constitute unfair methods of competition in violation of Section 5 of the FTC Act, 15 U.S.C. § 45. The violations or the effects thereof, as herein alleged, are continuing and will continue or recur in the absence of the relief herein requested, and were and are all to the prejudice and injury of the public.

19 In 1997, Mylan embarked on a strategy to raise the price, and thereby increase the profitability of some of its generic drugs by seeking from its API suppliers, long-term exclusive licenses for the DMFs of certain APIs selected by Mylan because of limited competition. If Mylan obtained such an exclusive license, no other generic drug manufacturer could use that supplier's API to make the drug in the United States. [REDACTED]

Dec-22-98 04:31pm From: ROGERS & WELLS SUPPORT SERVICES

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T-067 P 29/85 F-080

[REDACTED]  
[REDACTED]  
20 [REDACTED]  
[REDACTED]  
[REDACTED]

Ultimately, Mylan sought exclusive licenses for the DMFs for lorazepam API and clorazepate API as well as one other drug which is not the subject of this complaint.

21 Mylan began negotiating for exclusive licenses with Profarmaco and its distributor Gyma, which sold lorazepam and clorazepate APIs to Mylan. The parties negotiated at meetings in Bologna, Italy, [REDACTED] in London [REDACTED] and in New York, [REDACTED].

[REDACTED] These negotiations concerned Mylan's proposal to Profarmaco that it license exclusively to Mylan, for 10 years, Profarmaco's DMFs for lorazepam API and clorazepate API. The exclusive licenses would provide Mylan complete control over Profarmaco's entire supply of lorazepam and clorazepate API entering the United States market.

22 Prior to these negotiations, Gyma sold Profarmaco's lorazepam API to Mylan, Watson Pharmaceuticals, Inc. ("Watson"), and Purepac, a subsidiary of Faulding, Inc. ("Purepac"), and its clorazepate API to Mylan and Watson. Purepac and Watson are generic drug producers that compete with Mylan. At this time, Profarmaco (through Gyma) was the only source selling lorazepam and clorazepate API to generic manufacturers in the United States. FIS, which previously had supplied the U.S. market with lorazepam API, recently had exited the market because it no longer had any customers. With complete control of Profarmaco's supply of



DEC-22-98 04:32PM FROM: ROGERS &amp; WELLS SUPPORT SERVICES

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T-067 P. 30/85 F-020

these products, and by obtaining for itself any rights to control them. Mylan would deny its competitors access to the most important ingredient for producing lorazepam and clorazepate tablets.

23 In return for the ten-year exclusive licenses, Mylan offered to pay Cambrex, Profarmaco, and Gyma a percent of gross profits on sales of lorazepam and clorazepate tablets, regardless of whether Mylan purchased the API from Profarmaco through Gyma. The profit sharing percentage offered by Mylan was smaller for lorazepam than for clorazepate. As Mylan explained to Cambrex, Profarmaco, and Gyma, the reason for this difference was that Mylan intended to seek a similar exclusive agreement on lorazepam API with FIS, a competitor of Profarmaco, and with FIS's distributor, SST. Under this proposed agreement, Mylan also would pay FIS and SST a certain percent of Mylan's gross profits on lorazepam tablets, even though Mylan would not purchase FIS lorazepam API due to FDA regulations.

24 In October 1997, Mylan approached SST, FIS's distributor of lorazepam API in the United States, regarding a possible second exclusive licensing agreement for lorazepam API. The intent of this approach was to deny Mylan's competitors an alternate source of lorazepam API. Because of FDA regulations which require a manufacturer's ANDA to reference the DMF of its supplier, Mylan could not even use FIS's lorazepam API. Before Mylan could use FIS's product, it was required to supplement its ANDA, which would take an average of 18 months. Mylan explained to SST that it intended to raise the price of lorazepam tablets by controlling the supply of lorazepam API. In exchange for this exclusive license which would prevent any Mylan competitor from using FIS's lorazepam API, Mylan offered SST a percent of Mylan's gross profits on lorazepam tablets. Under this proposal, SST would receive these profits even though Mylan would not purchase from SST any lorazepam API. SST turned down Mylan's proposed

Dec-22-98 04:32pm From: ROGERS &amp; WELLS SUPPORT SERVICES

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T-067 P 31/85 F-080

licensing arrangement. Had SST accepted, none of Mylan's competitors would have been able to use FIS lorazepam API to make or sell lorazepam tablets in the United States.

25 Profarmaco and Gyma signed the ten year exclusive agreements licensing the two DMFs to Mylan on November 14, 1997. Through these agreements, Mylan obtained control over the supply of Profarmaco's APIs for lorazepam and clorazepate in the United States, denying Mylan's competitors (particularly Gyma's customers Watson and Purepac) access to these essential raw materials. In 1997, Profarmaco, through Gyma, supplied over 90% of the lorazepam API and 100% of the clorazepate API to generic manufacturers in the United States market.

26 Without a source of supply, Watson and Purepac [REDACTED] attempted to secure alternate API suppliers. Recognizing that Mylan now had control over lorazepam API from Profarmaco, Purepac even approached Mylan to obtain some lorazepam API on an emergency basis. Mylan refused to sell this product to Purepac.

27 Shortly after Mylan signed the ten year exclusive licensing agreements with Profarmaco, SST's president met in Pittsburgh, Pennsylvania, with the Mylan vice president who has responsibility for purchasing APIs. At this meeting, which occurred on or around November 20, 1997, SST explained to Mylan that it would not license FIS's DMF for lorazepam API to Mylan, at least in part out of concern that such an agreement could violate the antitrust laws.

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

28 On or around January 12, 1998, despite no significant increase in its costs, Mylan raised its price of clorazepate tablets to State Medicaid programs, wholesalers, retail pharmacy chains, and other customers by amounts ranging approximately from 1,900 percent to over 3,200 percent, depending on the bottle size and strength. For example, a 500-count bottle of 7.5 mg clorazepate tablets increased in price approximately from \$11.30 to \$377.00. On or around March 3, 1998, despite no significant increase in its costs, Mylan raised its price of lorazepam tablets by amounts ranging approximately from 1,900 percent to 2,600 percent, depending on the bottle size and strength. For example, a 500-count bottle of 1 mg lorazepam tablets increased in price approximately from \$7.30 to \$191.00. The ultimate retail price to consumers was even higher. Mylan's competitors matched these price increases for lorazepam and clorazepate tablets.

29 Shortly after Mylan raised its price of lorazepam tablets, and despite no significant increase in its costs, SST raised the price of FIS lorazepam API by approximately 19,000 percent. SST sold FIS's lorazepam API to Geneva -- one of Mylan's competitors. Geneva has set its price for lorazepam tablets at approximately Mylan's level.

30 As a result of these substantial and unprecedented price increases for lorazepam and clorazepate tablets, many purchasers, including pharmacies, hospitals, insurers, managed care organizations, wholesalers, government agencies, and others, have paid substantially higher prices. Moreover, some patients may have stopped taking lorazepam and clorazepate tablets altogether, or been forced to reduce the quantity they take, because they can not afford them.

Dec-22-08 04:33pm From:ROGERS &amp; WELLS SUPPORT SERVICES

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T-087 P 33/85 F-080

31 As a result of these substantial and unrecouped price increases on lorazepam and clorazepate tablets, Mylan, Camorex, Profarmaco, and Gvira have profited and continue to profit from their unlawful conduct to the detriment of consumers.

#### LACK OF PROCOMPETITIVE JUSTIFICATION

32 The exclusive licensing agreements, and defendants' other conduct intended to lock-up the supply of lorazepam and clorazepate API, lack any legitimate business or procompetitive justification. Moreover, any justification that may exist does not outweigh the substantial anticompetitive effects of defendants' conduct.

33 The exclusive licensing agreements were not reasonably necessary to protect Mylan's supply of lorazepam and clorazepate API [REDACTED]. [REDACTED] Profarmaco never indicated that it was considering no longer making either of these products. Even if Mylan had legitimate concerns about the supply of lorazepam API, like other generic pharmaceutical manufacturers, Mylan could have entered into a less restrictive requirements contract which would have assured Mylan a source of supply, but not denied Mylan's competitors access to the same source. Moreover, its attempt to obtain an exclusive agreement with FIS would provide no assurances of supply given that Mylan could not use any FIS lorazepam API for at least a year, due to FDA regulations.

#### THE EFFECTS OF DEFENDANTS' CONDUCT

34 The acts and practices of the defendants as herein alleged have had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition in the following ways, among others:

1. Raising the cost of production of the generic lorazepam and clorazepate APIs and tablets;
- (b) Raising the cost that pharmacies, hospitals, insurers, managed care organizations, wholesalers, government agencies, consumers, and others pay for lorazepam and clorazepate tablets;
- (c) Depriving consumers of access to needed pharmaceuticals and thereby injuring their health; and
- (d) Depriving consumers of the benefits of competition among generic pharmaceutical manufacturers and entry from new competitors.

FIRST COUNT

Agreement in Restraint of Trade on Lorazepam

35. The Commission realleges and incorporates by reference paragraphs 1 through 34
36. Mylan's exclusive licensing agreement with Cambrex, Profarmaco, and Gyma, pursuant to which Mylan obtained the exclusive right to Profarmaco's supply of lorazepam API, unreasonably restricts competition.
37. Under this licensing agreement, Mylan licensed, on a ten year exclusive basis, Profarmaco's lorazepam API. The purpose and effect of this agreement is to foreclose substantially the supply of lorazepam API to Mylan's competitors, thereby restraining trade and competition in the generic lorazepam tablets market and enabling Mylan to raise prices significantly.

35 This agreement is not reasonably necessary to accomplish any procompetitive objective. Moreover, any justification that may exist does not outweigh the substantial anticompetitive effect of defendants' conduct.

36 By entering into this unlawful exclusive licensing agreement for the supply of lorazepam API, defendants Mylan, Cambrex, Profarmaco, and Gyma have engaged in unfair methods of competition in or affecting commerce, in violation of Section 5 of the FTC Act.

**SECOND COUNT**

**Agreement in Restraint of Trade on Clorazepate**

40 The Commission realleges and incorporates by reference paragraphs 1 through 34

41 Mylan's exclusive licensing agreement with Cambrex, Profarmaco, and Gyma, pursuant to which Mylan obtained the exclusive right to Profarmaco's supply of clorazepate API, unreasonably restricts competition.

42 Under this licensing agreement, Mylan licensed, on a ten year exclusive basis, Profarmaco's clorazepate API. The purpose and effect of this agreement is to foreclose substantially the supply of clorazepate API to Mylan's competitors, thereby restraining trade and competition in the generic clorazepate tablets market and enabling Mylan to raise prices significantly.

43 This agreement is not reasonably necessary to accomplish any procompetitive objective. Moreover, any justification that may exist does not outweigh the substantial anticompetitive effect of defendants' conduct.

45 In entering into the exclusive license and profit sharing agreement for the supply of  
lorazepam API, defendants Mylan, Cambrex, Profarmaco, and Gyma have engaged in unfair  
methods of competition in or affecting commerce in violation of Section 5 of the FTC Act.

### THIRD COUNT

#### Conspiracy to Monopolize Generic Lorazepam Tablets Market

46 The Commission realleges and incorporates by reference paragraphs 1 through 34

47 Mylan, Cambrex, Profarmaco, and Gyma conspired to act together to obtain  
monopoly power for Mylan in the generic lorazepam tablets market in the United States.

48 Mylan acted with a specific intent to monopolize, and to destroy competition in,  
the generic lorazepam tablets market. Mylan devised and implemented a calculated campaign to  
raise the price and profitability of lorazepam by locking up the supply of lorazepam API, the most  
essential ingredient for making lorazepam tablets. Each of the co-conspirators acted with the  
specific intent that Mylan obtain monopoly power in the generic lorazepam tablets market, and  
through their profit sharing arrangement and the resulting higher prices, the co-conspirators each  
have profited significantly from their conspiracy to the detriment of consumers.

49 In furtherance of this conspiracy, these defendants entered into an agreement and  
profit sharing arrangement whereby Mylan obtained the exclusive license to Profarmaco's  
lorazepam API. This license had the purpose and effect of denying, to Mylan's competitors in the  
generic lorazepam tablets market, the supply of an essential raw material. Also in the furtherance  
of this conspiracy, Mylan -- with the full knowledge and approval of Cambrex, Profarmaco, and

DEC-22-08 04:34pm FROM: KUMERS &amp; WELLS SUPPORT SERVICES

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T-067 P 37/85 R-090

Clonazepam tablets, and the exclusive right to the supply of lorazepam API to generic manufacturers.

49 Defendants' conspiracy to monopolize the generic lorazepam tablets market had the effect of harming the competitive process. By entering into the exclusive licensing agreement, the conspirators prevented certain competitors from obtaining lorazepam API, enabling Mylan to significantly raise prices of generic lorazepam tablets. Had SST agreed to Mylan's proposal, it would have denied lorazepam API to other competitors and potential competitors, allowing Mylan to acquire or maintain monopoly power in the generic lorazepam tablets market.

50 By entering into a conspiracy to monopolize the generic lorazepam tablets market, defendants Mylan, Camorex, Profarmaco, and Gyma have engaged in unfair methods of competition in or affecting commerce in violation of Section 5 of the FTC Act.

#### FOURTH COUNT

##### Conspiracy to Monopolize Generic Clorazepate Tablets Market

51 The Commission realleges and incorporates by reference paragraphs 1 through 34

52 Mylan, Camorex, Profarmaco, and Gyma conspired to act together to obtain monopoly power for Mylan in the generic clorazepate tablets market in the United States.

53 Mylan acted with a specific intent to monopolize, and to destroy competition in, the generic clorazepate tablets market. Mylan devised and implemented a calculated campaign to raise the price and profitability of clorazepate by locking up the supply of clorazepate API, the most essential ingredient for making clorazepate tablets. Each of the co-conspirators acted with the specific intent that Mylan obtain monopoly power in the generic clorazepate tablets market.



Dec-22-98 04:34pm From:ROGERS &amp; WELLS SUPPORT SERVICES

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T-067 P. 38/85 F-080

and through the profit sharing arrangement and the resulting higher prices, the co-conspirators each have profited significantly from their conspiracy to the detriment of consumers.

54 In furtherance of this conspiracy, these defendants entered into an agreement and profit sharing arrangement whereby Mylan obtained the exclusive license to Profarmaco's clorazepate API. This license had the purpose and effect of denying to Mylan's competitors in the generic clorazepate tablets market, the supply of an essential raw material. Also in the furtherance of this conspiracy, Mylan approached [REDACTED]

55 Defendants' conspiracy to monopolize the generic clorazepate tablets market had the effect of harming the competitive process. By entering into the exclusive licensing agreement, the conspirators prevented certain competitors from obtaining clorazepate API, enabling Mylan to significantly raise prices of generic clorazepate tablets.

56 By entering into a conspiracy to monopolize the generic clorazepate tablets market, defendants Mylan, Cambrex, Profarmaco, and Gyma, have engaged in unfair methods of competition in or affecting commerce, in violation of Section 5 of the FTC Act.

#### FIFTH COUNT

##### **Monopolization of Generic Lorazepam Tablets Market**

57 The Commission realleges and incorporates by reference paragraphs 1 through 34

DEC-22-98 04:35PM FROM:RULERS &amp; RELS SUPPORT SERVICES

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1-067 P 39/85 F-090

58 Mylan obtained its monopoly power in the generic lorazepam tablets market. Using this monopoly power, Mylan raised the price of generic lorazepam tablets by amounts ranging approximately from 1,400 percent to 2,600 percent, depending on the bottle size and strength.

59 Mylan willfully acquired its monopoly power by entering into an exclusive licensing agreement for Profarmaco's lorazepam API. This exclusive license provided Mylan complete control over Profarmaco's supply of lorazepam API in the United States market, which enabled Mylan to deny its actual or potential competitors access to this essential ingredient for producing generic lorazepam tablets and to significantly raise prices.

60 Mylan's monopolization of the generic lorazepam tablets market constitutes an unfair method of competition in or affecting commerce, in violation of Section 5 of the FTC Act.

#### SIXTH COUNT

##### Attempted Monopolization of Generic Lorazepam Tablets Market

61 The Commission realleges and incorporates by reference paragraphs 1 through 34

62 Mylan acted with a specific intent to monopolize, and to destroy competition in, the generic lorazepam tablets market. Mylan devised and implemented a calculated campaign to raise the price and profitability of lorazepam by locking up the supply of lorazepam API, the most essential ingredient for making generic lorazepam tablets.

63 Mylan has willfully engaged in a course of exclusionary conduct in order to obtain a monopoly in the generic lorazepam tablets market, including, *inter alia*: (1) entering into an exclusive licensing agreement for Profarmaco's lorazepam API, and (2) approaching SST -- the

Dec-22-98 04:35pm From: ROGERS &amp; WELLS SUPPORT SERVICES

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T-067 P 40/85 F-000

only other active manufacturer of lorazepam API to generic manufacturers in the United States -- proposing a similar licensing arrangement for FIS's lorazepam API even though Mylan could not use any of FIS's lorazepam API because of FDA regulations.

64 At the time Mylan engaged in these acts, it had a dangerous probability of succeeding in controlling the supply of lorazepam API and excluding its competitors. Mylan, by obtaining the exclusive licensing agreement with Camorex, Profarmaco, and Gyna, prevented certain competitors from obtaining lorazepam API, enabling Mylan to significantly raise prices. Had SST agreed to Mylan's proposal, it would have denied lorazepam API to other competitors and potential competitors, allowing Mylan to acquire or maintain monopoly power in the generic lorazepam tablets market.

65 Mylan's attempt to monopolize the generic lorazepam tablets market constitutes an unfair method of competition in or affecting commerce in violation of Section 5 of the FTC Act.

#### SEVENTH COUNT

##### Monopolization of Generic Clorazepate Tablets Market

66 The Commission realleges and incorporates by reference paragraphs 1 through 34

67 Mylan obtained monopoly power in the generic clorazepate tablets market. Using this monopoly power, Mylan raised the price of generic lorazepam tablets by amounts ranging approximately from 1,900 percent to 3,200 percent, depending on the bottle size and strength.

68 Mylan willfully acquired its monopoly power by entering into an exclusive licensing agreement for Profarmaco's clorazepate API. This exclusive license provided Mylan complete control over Profarmaco's supply of clorazepate API in the United States market, which

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enabled Mylan to deny its actual or potential competitors access to this essential ingredient for producing generic clorazepate tablets and to significantly raise prices.

69 Mylan's monopolization of the generic clorazepate tablets market constitutes an unfair method of competition in or affecting commerce in violation of Section 5 of the FTC Act.

#### EIGHTH COUNT

##### Attempted Monopolization of Generic Clorazepate Tablets Market

70 The Commission realleges and incorporates by reference paragraphs 1 through 34

71 Mylan acted with a specific intent to monopolize, and to destroy competition in, the generic clorazepate tablets market. Mylan devised and implemented a calculated campaign to raise the price and profitability of clorazepate by locking up the supply of clorazepate API, the most essential ingredient for making clorazepate tablets.

72 Mylan has willfully engaged in a course of exclusionary conduct in order to obtain a monopoly in the generic clorazepate tablets market, including, *inter alia* (1) entering into an exclusive licensing agreement for Profarmaco's clorazepate API, and (2) [REDACTED]

[REDACTED]

73 At the time Mylan engaged in these acts, it had a dangerous probability of succeeding in controlling the supply of clorazepate API and excluding its competitors. Mylan, by obtaining the exclusive licensing agreement with Cambrex, Profarmaco and Gyma, prevented certain competitors from obtaining clorazepate API, enabling Mylan to significantly raise prices.

74. Mylan's attempt to monopolize the generic oral contraceptives market constitutes an unfair method of competition and affecting commerce in violation of Section 5 of the FTC Act.

**THE COURT'S POWER TO GRANT RELIEF**

75. Section 13(b) of the FTC Act empowers this Court to issue injunctive relief against violations of the FTC Act and, in the exercise of its equitable jurisdiction, to order other ancillary equitable relief, including disgorgement and restitution, to remedy the injury caused by defendants' violations.

**PRAYER FOR RELIEF**

WHEREFORE the Commission requests that this Court, as authorized by 15 U.S.C. § 53(b) and 15 U.S.C. § 26, and pursuant to its own equitable powers, enter final judgment against each

Defendant declaring, ordering, and adjudging:

1. That Defendants Mylan, Cambrex, Profarmaco, and Gyma violated Section 5(a) of the FTC Act;

2. That Defendants Mylan, Cambrex, Profarmaco, and Gyma be permanently enjoined from engaging in conduct violating Section 5(a) of the FTC Act;

3. That the Court rescind defendants' unlawful licensing arrangements.

Dec-22-98 04:36pm From: ROGERS & WELLS SUPPORT SERVICES

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4 That the Court grant such other equitable relief, including disgorgement and restitution in an amount exceeding \$120 million plus interest, as the Court finds necessary to redress and prevent recurrence of defendants' violations of Section 5(a) of the FTC Act as herein alleged

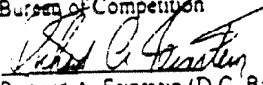
RESPECTFULLY SUBMITTED.

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Health Care Services and Products Division  
Federal Trade Commission  
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Washington, D.C. 20580

Dated December 21, 1998  
Washington, D.C.

**FILED**

JAN 13 1999

NANCY MAYER-WHITTINGTON, CLERK  
U.S. DISTRICT COURT

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION,

Plaintiff,

V.

MYLAN LABORATORIES, INC., CAMBREX  
CORPORATION, PROFARMACO S.R.L., and GYMA  
LABORATORIES OF AMERICA, INC.,

**Defendants.**

: Case Number 1:98CV03114

: Hon. Thomas F. Hogan

## STIPULATION

IT IS HEREBY STIPULATED AND AGREED, by and between the undersigned counsel for the parties, that defendants' time to move, answer or otherwise respond to plaintiff's Complaint is extended to and including February 23, 1999.

**ROGERS & WELLS LLP**

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## FEDERAL TRADE COMMISSION

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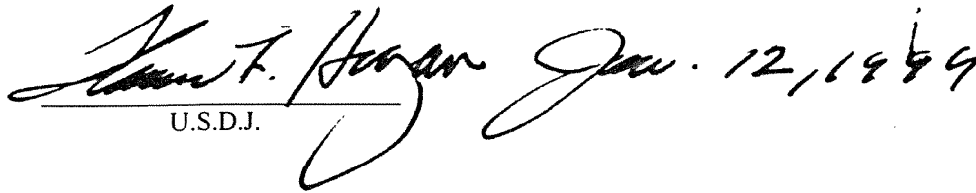
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Counsel for Defendants Cambrex Corporation  
and Profarmaco S.R.L.

NYA 156668.1

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SO ORDERED:

  
U.S.D.J.



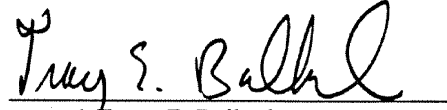
CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Stipulation was sent via Federal Express on this 11<sup>th</sup> day of January, 1999 to:

Richard Feinstein, Assistant Director  
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